

Draft Minutes
Registration Review Workgroup Meeting
Pesticide Program Dialogue Committee
Sheraton Crystal City
July 16, 2003

Participants:

EPA: Jay Ellenberger, Betty Shackleford, Richard Dumas, Vivian Prunier, Margie Fehrenbach

Workgroup Members: Cindy Baker, Britt Bailey (via teleconference), Carolyn Brickey, Patti Bright, Sue Crescenzi, Ted Head, Steve Kellner, Gary Libman (via teleconference), Therese Murtaugh; Bob Rosenberg, Troy Seidel, Julie Spagnoli, Roberta Spitko, Warren Stickle, Ray McAllister (substituting for Jay Vroom), George Wichterman, Eric Olson, and Dan Botts.

Minutes of the July 2 teleconference were amended to add the name of Steve Kellner as a participant in the conference.

Lessons Learned from Reregistration

- FIFRA section 4 clearly stated what registrants must do in Phases 2 and 3.
- The reregistration process imposed the same procedure for all ingredients. There was no way to abbreviate the procedure when a pesticide posed very little risk.
- Rules about what constituted the current standard of registration seemed to change while a pesticide was undergoing reregistration. Data gaps should be recognized early in the process. There was a concern that EPA required studies for which there is no clear protocol.
- When a pesticide in the reregistration program was also undergoing Special Review, the RED was delayed until completion of the Special Review. "Speed bumps" that delayed completion of a RED included law suits and disputes over data.
- After the RED for an active ingredient, end-use products are reregistered. But follow through has not been systematic. For example, product labels are often not consistent with the RED or with the Agency's labeling policies. Agency doesn't track or report the completion of product reregistration.
- Reregistration was not open enough for non-registrants (particularly public interest groups) to participate early in the process. Early involvement of CDC or others knowledgeable about public health uses of a pesticide would have been helpful. Early involvement of Fish and Wildlife Service regarding endangered species issues and growers or other stakeholders regarding use practices would have been useful.

- Publishing reregistration schedules in advance and a clearly delineating public participation procedure worked well for registrants.
- Suggested it would be helpful to have CDC and the Public Health Corps participate in the Workgroup.

Scope of Registration Review

- What is a Registration Review Decision? Is it an assessment *whether* a pesticide meets current standards of registration or is it a process that must be pursued until resolution of all issues regarding the continued registration of the pesticide?
 - If it is the former, the review would focus on changes that have occurred since the last review of the pesticide. Issues identified in the registration review would be pursued under “other provisions of the Act.” For example pesticides with risk issues could be referred to special review.
 - If it is the latter, EPA will not be able to complete registration reviews on 80 chemicals per year.
- What is EPA supposed to review? The options are:
 - individual end-use product on the 15th anniversary of its original registration;
 - each active ingredient;
 - groups of chemically related active ingredients, e.g. reregistration cases;
 - group active ingredients by some other criteria, e.g., chemicals that share a common mechanism of toxicity, or pesticides used for a common purpose such as corn herbicides.

The group favored the chemical case approach, but needed more discussion of how to set the anniversary date for a chemical case as individual members of the case would have different dates of initial registration.

The group suggested that end-use products should be considered in registration review but were not certain how to do this.

Should 24(c) registrations, EUPs and section 18 emergency exemptions be included even though these uses are not section 3 registrations?

Participants questioned how to approach registration review of products that contain multiple active ingredients.

- Inclusion of inert ingredients in registration review. Participants offered a range of opinions:
 - Inert ingredients aren’t registered, so they should not be considered in registration review;

- Consider inert ingredients when reviewing end-use products;
- Use other procedures to manage issues relating to inert ingredients, e.g., classify the ingredient as a “List One Inert” (i.e., inert ingredient that must be identified on the product label).
- Update 40CFR Part 158 so registrants know what the requirements are.
- What should be the basis of a decision that a pesticide’s registration meets current standards? Participants offered a range of opinions:
 - A determination that it meets all the requirements of 40 CFR Part 158;
 - A determination that end-use product labels are consistent with the pesticide’s current risk assessment and labeling policy;
 - Focus on what has changed since the last assessment of the pesticide with respect to new data requirements and/or changes in risk standards. Look at all areas, e.g., even recently completed tolerance assessments, to see if anything has changed.
 - Registration review is not intended to be a comprehensive review like reregistration or tolerance reassessment.
- Mechanisms for keeping a pesticide’s registration up to date. Participants identified several approaches for assuring that a pesticide’s registration meets current standards:
 - When it reviews a new use application, the Agency should review the entire label, not just the proposed addition, and insist that all aspects of the label be brought to current standards.
 - When it reviews a new use application, the Agency should assure that the data supporting the pesticide is consistent with current standards.
 - When the Agency identifies a new data requirement, or new data requirements are imposed by legislation such as the endocrine disruptor tests, the Agency should conduct special data call-ins to acquire the data. Otherwise the data won’t be available for the registration review.
 - The Agency could conduct label improvement programs to bring labels to current standards. Otherwise, labels would have to be updated during (or as a result of) registration review. This could result in an uneven playing field as the labels of competing products would not be updated until they undergo registration review.
 - Submit exposure information (i.e., non-guideline data) so that it is available when the pesticide begins its registration review.

Scheduling Registration Reviews

- Participants generally agreed that there should be clear and predictable schedules for registration reviews. Stakeholders need to know when the clock starts.
- Criteria for scheduling registration reviews:

- Participants generally agreed that setting schedules by date of last comprehensive review would result in a stable, predictable, and largely workable schedule.
 - Other participants proposed scheduling the worst first. Participants acknowledged that it might be difficult to decide what attributes should be used in deciding which pesticides are “the worst.” It was noted that the risks posed by pesticides registered prior to 1985 were addressed in the reregistration and tolerance reassessment programs.
 - Some participants suggested that pesticides with the oldest and least comprehensive reviews be scheduled first: pesticides with no REDs (i.e., registered after 1984) and no tolerance reassessment; pesticides with no REDs, but with tolerance reassessment; and pesticides with REDs but no tolerance reassessment.
 - New testing requirements should be considered in setting priorities for registration review.
- The Workgroup asked the Agency to provide a list of active ingredients, grouped by chemical case and ranked by date of initial registration.

Public Participation in Registration Review

- The registration review process should be clear and understandable. Stakeholders should know when they will be able to participate in the process.
- Information should be publically available on the Agency’s website.
- All stakeholders should be able to participate from the outset of the process.
- There should be a clear accounting scheme to show what has been completed.

Action Items

- Cindy Baker will draft a paper on scope of registration review and e-mail it to workgroup members.
- Sue Crescenzi will draft a paper on scheduling options and e-mail it to workgroup members.
- EPA will provide list of active ingredients ranked by date of initial registration.

Next Meetings

- Teleconference on Monday, August 11 from 2 to 4 p.m. EDT.
- Teleconference on Wednesday, September 24 from 2 to 4 p.m EDT.

- Meeting on Thursday, October 16 from 9 a.m. to 5 p.m. in Crystal City.